

REMARKS

Claims 85 and 86 are pending in the application.

- All previous objections and rejections have been withdrawn in view of remarks presented in the Response dated May 06, 2010.
- Claims 85 and 86 are newly rejected under 35 USC 102(b) as being anticipated by Cordell as evidenced by a reference from the Australian Proteome Analysis Facility, submitted as Exhibit A in Remarks filed 6/13/2008.
- Claims 85 and 86 are newly rejected under 35 USC 102(a) as being anticipated by Schenk, et al. (WO 99/27944) as evidenced by a reference from the Australian Proteome Analysis Facility, submitted as Exhibit A in Remarks filed 6/13/2008.
- Claims 85 and 86 are newly rejected under 35 USC 103(a) as being unpatentable over Wong, et al., PNAS, 82:8729 – 8732 (1985), in view of Schenk, et al.

Rejection under USC 35, 102(b)

Claims 85 and 86 are newly rejected under 35 USC 102(b) as being anticipated by Cordell as evidenced by a reference from the Australian Proteome Analysis Facility, submitted as Exhibit A in Remarks filed 6/13/2008. The Applicant respectively traverses this rejection.

The Examiner states Cordell teaches “an in vitro method of diagnosing familial amyloidosis or Alzheimer’s disease comprising providing a serum sample from a patient which contains circulating beta-amyloid in the presence of human serum albumin from a patient ... treating said sample to a “panel of beta-amyloid antibodies” and then analyzing the samples “using solid-phase ELISA techniques.” Pending Action, pages 4 and 5.

For a reference to be anticipatory it must teach explicitly or inherently each element of the claimed invention. MPEP, 2131. Cordell does not meet this standard. The present invention requires the formation of an immune complex in the presence of physiological levels of human serum albumin (or 60 mg/ml of human serum albumin). However, and unlike the present invention, the Examiner has not shown that Cordell teaches this limitation. Rather, Cordell teaches immunological complexes being made in “solid-phase ELISA assays” and not in the presence of physiological levels of human serum albumin. ELISA assays typically require the dilution of the sample to be tested by 1:100 to 1:10,000. Thus, the concentration of serum albumin in the ELISA cannot be in the presence of physiological (or 60 mg/ml) of human serum

albumin, as is presently claimed. Thus, Cordell can not be anticipatory to the presently claimed invention. In view of the proffered remarks, the Applicant respectfully requires that the pending rejection be withdrawn.

Rejection under USC 35, 102(a)

Claims 85 and 86 are newly rejected under 35 USC 102(b) as being anticipated by Schenk as evidenced by a reference from the Australian Proteome Analysis Facility, submitted as Exhibit A in Remarks filed 6/13/2008. The Applicant respectfully traverses this rejection.

As noted by the Examiner in the pending Office Action, the effective date of the Schenk publication is six days before the priority date of the pending application. A Declaration was submitted under 37 CFR 1.131 on September 8, 2004 effective to remove this reference from consideration (cover pages attached; see file history for supporting data filed with the Declaration). The supporting data consisted of a draft of the submitted application written prior to the filing date of the Schenk reference. Support for pending Claims 85 and 86 can be found on pages 20 – 22 of the draft specification as submitted to the USPTO on September 8, 2004 (copy of pages 20 – 22 attached). In view of the showing by the Applicant, it is respectfully submitted that the pending rejection is moot.

Rejection under USC 35, 103(a)

Claims 85 and 86 are newly rejected under 35 USC 103(a) as being unpatentable over Wong, et al., PNAS, 82:8729 – 8732 (1985), in view of Schenk, et al. The Applicant respectfully traverses this rejection.

Wong is cited as teaching “a method for forming an immune complex comprising providing an [sic] residues 1 – 10 of A β in vivo, forming an immune response which produces an antibody generated against said epitope and detecting the resulting antibodies in the serum.” Pending Action, page 7. First, the work of Wong is conducted in mice and, therefore, can not comprise “human serum albumin,” as is presently claimed.

Second, the generation of an immune response and the generation of antibodies does not necessitate the formation of an immune complex of an antigen and an antibody, as is presently claimed. An immune response, for example, may be a non-antibody based innate response. Further, antibodies are typically produced in an organism where it is unlikely that an immune complex would form since the formation of immune complexes in the production organism 1) may be detrimental to that organism and 2) would make the antibodies extremely difficult to recover.

Third, the only definitive formation of an immune complex of any sort in Wong is in an ELISA assay and, as discussed above, it is not in the presence of physiological (or 60 mg/ml) of human serum albumin, as is presently claimed. ELISA assays typically require the dilution of the sample to be tested by 1:100 to 1:10,000. Thus, the concentration of serum albumin in the ELISA cannot be in the presence of physiological (or 60 mg/ml) of human serum albumin, as is presently claimed.

The Examiner states that Wong does not teach "an antibody generated against the central region of beta amyloid SEQ ID NO.: 3." The Applicant agrees. However, the secondary reference that the Examiner relies upon for providing this teaching (Schenk) has been removed as prior art as discussed above via a 1.131 Declaration. Thus, Wong in view of Schenk can not teach, fairly suggest or render predictable the presently claimed invention.

In view of the forgoing, the Applicant respectfully requests the withdrawal of the pending rejection and allowance of the claims.

Summary

In light of the above amendment and attendant remarks, consideration of the subject patent application is respectfully requested. If an interview would be beneficial to the prosecution of this case, Applicants respectfully request that Examiner MacFarlane contact the representatives of record. Any deficiency or overpayment should be charged or credited to Deposit Account No. 50-4514.

Respectfully submitted,

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